REMARKS

The foregoing amendments and the following remarks are submitted in response to the communication dated February 17, 2004.

Status of the Claims

Claims 1-33 are pending in the application. Claims 27-33 are withdrawn from consideration. Claims 1-26 are rejected. Claims 1-7, 11, 16, 17 have been amended in order to more particularly point out and distinctly claim that which Applicants regard as the invention. Support for the amended claims can be found generally through Applicants' specification. Claims 9 and 26 are canceled.

Objection to the Specification

The Examiner objects to the specification because at page 8, line 11, "sepharose" is not capitalized. Applicants herein correct this inadvertent error.

Objection to the Claims

The Examiner objects to claims 3-4 because they do not end with a period. Applicants herein correct this inadvertent error.

The Examiner objects to claims 1 and 16-17 because each of these claims fails to indent each of the recited active verb steps. Applicants herein correct this inadvertent error.

Particularity and Distinctiveness of the Claims

The Examiner rejected claims 2-7 and 9-26 under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter applicant regards as the invention.

The Examiner maintains that the term *"highly unsaturated fatty acids"* in claims 2-7 is unclear. The relevant acids are more fully described in the specification in the text bridging pages 4 and 5. Hence, Applicants maintain that the term *"fatty acids released by the action of type IV cPLA$_2$"* is clear to those of skill in the art, however, the Examiner considers this definition indefinite also. Accordingly, in the interest of securing rapid allowance of a patent, Applicants herein change the claim language to recite *"fatty acids having three or more carbon-carbon double bonds"*, a term that is clearly and undisputably understood as clear by those skilled in the art.

The Examiner rejects claim 11 because the term *"concentration is increased"* allegedly is unclear regarding which quantity this concentration is compared to. Accordingly, Applicants herein recite *"relative to normal levels"* in claim 11 to further clarify the claim language. Support for this recitation may be found in the specification at page 6, line 12, among other places.

The Examiner rejects claims 14-15 because the recitation "*the type IV cPLA$_2$ protein*" lacks antecedent basis. Applicants herein insert "protein" after "cPLA$_2$" into claim 1 as the Examiner suggests thereby obviating the rejection.

The Examiner rejects claims 16-17, 19-21, 24 and 26 alleging that "*detecting*" and "*detected*" are unclear since claim 1 recites "examining" instead. Applicants herein amend claim 1 to recite "detecting" in accordance with the later claims thereby obviating this rejection. Applicants also insert "further" into claim 16 clarifying that an additional step is recited.

The Examiner rejects claim 17 because the recitation "*the other blood components*" allegedly lacks antecedent basis and because it is allegedly unclear how the steps of "separating," "disrupting," and "detecting" fit into the sequence of "obtaining" and "examining." Applicants herein change claim 1 to recite "detecting" in accordance with the subsequent claims. Further, Applicants herein include the recitation "*after obtaining the sample of red blood cells and prior to detecting the proteins*" to further clarify the sequence of events.

No issue of new matter arises by way of these changes since those of ordinary skill in the art would readily appreciate the sequence of events and would understand that "examining" and "detecting" may be used interchangeably.

The Examiner rejects claim 26 because of the term "*substrate assay.*" Applicants herein cancel the subject claim without prejudice thereby obviating the rejection.

The Specification Fully Enables the Claimed Invention

The Examiner rejects claims 1-26 under 35 U.S.C. 112, first paragraph, contending that the specification does not enable any person skilled in the art to which it pertains, or with which it is most connected, to make and use the invention commensurate in scope with these claims. The Examiner's rejection is based upon two technical aspects as follows:

(1) The scope of the blood sample; and

(2) The scope of the assay with respect to whether an antibody to type IV $cPLA_2$ or a homologue thereof is employed.

Regarding scope of the blood sample

Applicants herein change the claim language to recite *"obtaining a sample of red blood cells separated from whole blood* " thereby excluding the use of whole blood. The basis for this change can be found on page 3, lines 14-15 of the specification, among other places. Therefore no issue of new matter occurs because of this amendment. Applicants expressly maintain that in practice, some near-patient testing methods likely use a separation step to remove platelets and white blood cells, for example by trapping platelets and white blood cells using antibodies on a membrane. Such embodiments are intended within the scope of the claims. Accordingly, the language of claims 1, 5, 6 and 7 are changed to include the above-noted recitation. Claim 9 is deleted as redundant, and claim 8, which refers to the complete isolation of the red blood cells, is maintained.

Regarding the scope of the type IV $cPLA_2$ Protein assay method

The Examiner argues that the present claims extend to *all* assays that detect type IV $cPLA_2$, while the specification allegedly only discloses immunoassays that employ an antibody against type IV $cPLA_2$. Accordingly, the Examiner considers the description not to support the breadth of the claims. The Examiner considers that the specification at page 2, lines 25-33 states that other assays are not capable of distinguishing between different forms of PLA_2 enzyme.

Applicants maintain that certain substrate assays, notably those using radiolabelled substrates and detecting specific radioactive products, are capable of specifically measuring type IV $cPLA_2$ in cells. However, as immunoassays are the most commercially viable means of detecting type IV $cPLA_2$, Applicants herein change the claim language to specifically recite immunoassays that use antibodies against type IV $cPLA_2$. Accordingly, claims 1, 5, 6 and 7 are adapted to recite that the detection is performed with an antibody to type IV $cPLA_2$. Claims 19-25, which refer to generic and specific immunoassays, are maintained as reciting particular embodiments within the scope of the broader claims. In view of the foregoing remarks, Applicants submit that the Examiner's rejection under 35 U.S.C. 112, first paragraph may properly be withdrawn.

The presently claimed subject matter is novel over the prior art

The Examiner rejects claims 1, 16-18 and 26 under 35 U.S.C. 102(b) as anticipated by Filimonkova (RU 200509). As noted, *supra*, Applicants have specifically recited "protein" to clarify further that the intended assays are directed to detecting type IV cytosolic phospholipase A_2 ($cPLA_2$) and have changed "examining" to "detecting". Applicants understand that the instant rejection is made because the Examiner did not consider the original claims to be limited to the *specific* detection of type IV $cPLA_2$. As the claim language is changed herein thereby clearly excluding assays that do not enable the *specific* detection of type IV $cPLA_2$ with an antibody to type IV $cPLA_2$. RU 200509 does not teach or suggest specifically detecting type IV $cPLA_2$ with an antibody to the same.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Early and favorable action on the claims is earnestly solicited.

Respectfully submitted,

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